

Stantonsburg Drug Company

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A. Rowland Strickland, Jr.
Registered Pharmacist



December 23, 2005

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852
FAX: 301.827.6870

Dear Sir or Madam

My name is Rowland Strickland, and I have been practicing pharmacy since 1971. I have been compounding for several years.

One of the significant areas of my compounding practice is the preparation of bio-identical hormones for women with severe menopausal symptoms. Quite often these women have failed to benefit from manufactured medication. In addition, many of them have experienced severe side effects from synthetic hormones that they didn't experience once they used compounded bio-identical hormones.

We require a 90-minute menopause consultation plus saliva test to objectively determine tissue hormone levels. This data plus the severity of their symptoms assessment forms the basis of our recommendation to the patient's physician as to an appropriate bio-identical hormone dosage. We recommend the lowest dose of estrogen (nearly always balanced with progesterone) and secure the physician's permission to titrate the dose up within a reasonable range if symptoms do not improve.

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Wyeth has filed a petition with the FDA that would restrict the ability of physicians to prescribe and pharmacists to prepare and patients to take bio-identical hormones. They make unsubstantiated, adverse claims about the safety and efficacy of bio-identical hormones while seemingly ignoring the multiple adverse effects of their equine estrogen and medroxyprogesterone.

This is not the first time that Wyeth has tried to use government intervention to protect its business and profits and deny women access to hormone therapies they need. Years ago, Wyeth fought successfully to get FDA to block generic forms of its Premarin from entering the US market. These generic versions would have slashed the cost to women for this therapy. Then as now, Wyeth used its money and muscle to argue that the competitive offerings were not safe, and they succeeded in keeping them off the market. The motivation was not improvement of women's health but pure GREED.

Wyeth is once again trying to insert itself into the doctor-pharmacist-patient relationship and make decisions for their own self-interest. Please reject the petition as not concerned with scientific evidence but totally concerned with making money.

Sincerely

Rowland Strickland
Registered Pharmacist
Stantonsburg Drug Company, Inc.